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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/065,330	04/23/98	WALKER	A 2500.097US2

EXAMINER	
SAOUD, C	
ART UNIT	**PAPER NUMBER**
1646	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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1- File Copy

Office Action Summary	Application No. 09/065,330	Applicant(s) WALKER et al.
	Examiner Christine Saoud	Group Art Unit 1646

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-6 and 9-12* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-6 and 9-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Claims 1 and 9 have been amended and claims 7, 8 and 13 have been canceled as requested in the amendment of paper #8, filed 15 October 1999. Claims 1-6 and 9-12 are pending in the instant application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the claims are directed to compositions, however, a composition requires the presence of at least two elements to be considered a composition. The claims as written only require the presence of a human phosphorylated prolactin mimic.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-6 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cooke et al. (U.S. Pat. No. 4,725,549) and A. M. Walker (TEM, 5(5): 195-200) in view of Maciejewski et al. (J. Biol. Chem. 270(17): 27661-27665, 1995.

Cooke et al. teach the recombinant production of prolactin (see Example 4 at column 10). Cooke et al. do not teach a nucleic acid encoding a prolactin with a substitution at the serine corresponding to position 179 of human prolactin. Walker teaches that a serine in prolactin, within the region of amino acids 170-180, is highly conserved between species and is a site of phosphorylation (see page 196, column 3). Walker also teaches that phosphorylated prolactin acts as a prolactin receptor antagonist, while nonphosphorylated prolactin stimulates cell proliferation (see page 197, column 2). Walker does not teach prolactin with a substitution at serine within the region of amino acids 170-180.

Maciejewski et al. teach the mutation of serine at amino acid position 90 of bovine prolactin with glutamic acid. This substitution mimics phosphorylation of the prolactin, such that the substituted prolactin acts as a prolactin receptor antagonist (see page 27664, Figure 5).

It would have been obvious to one of ordinary skill in the art to modify the recombinant prolactin of Cooke et al. by the substitution of another amino acid for serine in the region of amino acids 170-180 in the manner taught by Maciejewski et al. in order to create a prolactin receptor antagonist. One of ordinary skill in the art would be motivated to substitute another

amino acid which would mimic phosphorylation for this serine because Walker teaches that this serine is important for biological activity and phosphorylation creates a prolactin receptor antagonist. One would be motivated in substituting another amino acid, such as glutamic acid as was taught by Maciejewski et al., because this would create a prolactin which would mimic phosphorylated prolactin (without the disadvantage of possible dephosphorylation) and this substituted prolactin would be useful in antagonizing the prolactin receptor. The skilled artisan would have a reasonable expectation of success in obtaining a prolactin receptor antagonist by substituting another amino acid for the serine at amino acid position 170-180 because Maciejewski et al. successfully substituted another serine in bovine prolactin and obtained a similar result, absent clear and convincing evidence to the contrary.

Claims 3 and 4 recite substitution of the serine residue with aspartate. However, substitution with aspartate would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made because aspartate (aspartic acid) is considered a conservative amino acid substitution for glutamate (glutamic acid). Because Maciejewski et al. teach that substitution of serine with glutamic acid provides a prolactin molecule which mimics phosphorylated prolactin, one would have a reasonable expectation of success that substitution with aspartic acid would provide the same effect because they are very similar in structure and chemical properties, absent evidence to the contrary.

Claims 9-12 are directed to compositions of the phosphorylated prolactin mimic. However, compositions of a prolactin mutant which is substituted at serine 179 with another

amino acid would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made because Walker teaches that this serine is important for biological activity and phosphorylation creates a prolactin receptor antagonist which would be useful for antagonizing the prolactin receptor in an individual, absent evidence to the contrary.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 7AM to 3PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556. If this number is out of service, please call the Group receptionist for an alternate number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 15, 2000

CHRISTINE SAOUD
PATENT EXAMINER

Christine Saoud